BS ISO 18162:2024

BSI Standards Publication

Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells

Documents
Document Sharing Hub

Full document details: BS ISO 18162:2024

National foreword

This British Standard is the UK implementation of ISO 18162:2024.

The UK participation in its preparation was entrusted to Technical Committee BTI/1, Biotechnologies.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2024
Published by BSI Standards Limited 2024

ISBN 978 0 539 24387 1

ICS 07.080

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2024.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS ISO 18162:2024

International Standard

ISO 18162

First edition
2024-12

Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells

Biotechnologie — Biobanque — Exigences relatives aux cellules souches neuronales humaines dérivées de cellules souches pluripotentes

Reference number
ISO 18162:2024(en)

© ISO 2024

Documents
Document Sharing Hub

Full document details: BS ISO 18162:2024

COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Documents
Document Sharing Hub
Full document details: BS ISO 18162:2024

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **1**
4 Abbreviations ... **5**
5 General requirements ... **6**
5.1 General ... 6
5.2 Legal and ethical requirements ... 7
5.3 Personnel, facilities and equipment ... 7
5.4 Reagents, consumables and other supplies ... 7
5.5 Management of information and data ... 7
6 Collection of biological source materials and associated data to the establishment, characterization and QC of hPSCs ... **8**
7 Generation of hPSC-NSCs from hPSCs ... **8**
7.1 Processes ... 8
7.2 Unique identification ... 8
7.3 Testing for infectious agents ... 8
7.4 Generation of hNSCs and culture ... 8
7.5 Subculture and limited expansion ... 9
8 Characterization of hPSC-NSCs ... **9**
8.1 General ... 9
8.2 Viability ... 10
8.3 Morphology ... 10
8.4 Population doubling time and subculture/passage ... 11
8.4.1 PDT ... 11
8.4.2 Subculture/passage ... 11
8.5 Cell population purity ... 11
8.6 Proliferation ... 11
8.7 Differentiation capability — in vitro multi-cell type differentiation ... 12
8.7.1 General ... 12
8.7.2 In vitro neuronal and glial differentiation ... 12
8.8 Immunophenotyping by flow cytometry ... 12
8.9 Microbial contamination ... 13
8.10 Neural replacement and functional recovery ... 13
9 Quality control ... **14**
10 Storage ... **14**
11 Thawing ... **15**
12 Disposal ... **16**
13 Distribution of hPSC-NSCs — Information for users ... **16**
14 Transport of hPSC-NSCs ... **17**
14.1 General ... 17
14.2 hPSC-NSCs frozen in ampoules or cryovials ... 17
14.3 Living hNSC cultures ... 17
Annex A (informative) **Exemplary quality control test procedure for biobanking of hPSC-NSCs** ... **19**
Annex B (informative) **Examplary methods for the generation of hNSC from hPSCs** ... **20**
Bibliography ... **24**

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 18162:2024

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 276, *Biotechnology*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 18162:2024

Introduction

Neural stem cells (NSCs) are the adult stem cells in the central nervous system (CNS). NSCs have self-renewal ability and multipotency. NSCs can differentiate into various neurons and glial cells including astrocytes and oligodendrocytes. NSCs play a major role in embryonic development and adult neurogenesis. According to the hypothesis by Alvarez-Buylla, there are several types of cells can be called NSCs, including neuroepithelium – epithelial cells of the ventricular zone (VZ) of the neural tube[1], radial glial cells (RGCs) and basal (intermediate) progenitor cell (IPC)[2-4]. In the adult, NSCs are restricted to specific brain regions, such as the subventricular zone (SVZ) of the lateral ventricles and the subgranular zone (SGZ) of the dentate gyrus (DG) of the hippocampus[5].

NOTE The term "neural" refers to any type of nerve cell, including a mixture of brain cells, whereas "neuronal" is specifically related to neurons.

Despite these advances, substantial ambiguities persist regarding the nomenclature, nature, identity, function, mode of isolation and experimental handling of these cells. NSCs are not fully defined by the initial minimal criteria proposed out, and as such require careful characterization by a matrix of functional assays.

NSCs have been isolated from human fetal CNS (brain or spinal cord), cerebrospinal fluid, biopsy and autopsy material, or differentiated from pluripotent stem cells (PSCs), which are widely used for animal and clinical research[6]. NSCs generated from different sources or differentiation protocols have different properties. Different institutions use different practices for isolating, processing and biobanking these NSCs, making it difficult to compare data and results across institutions. Thus, there is a need for standardized approaches to isolate, process, expand and cryopreserve these NSCs.

The aim of this document is to provide general guidance for biobanking of human NSCs derived from pluripotent stem cells (hPSC-NSCs) for research purposes. This document is applicable for academic centers, public and private institutions performing a biobanking service of hPSC-NSCs for R&D (Research and Development) and preclinical studies, not for clinical use.

Importantly, this document is focused on hPSC-NSCs that have been isolated, manipulated and/or propagated from hPSCs in culture for research purposes.

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 18162:2024

Documents
Document Sharing Hub

Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells

1 Scope

This document specifies requirements for the biobanking of human neural stem cells (hPSC-NSCs) derived from human pluripotent stem cells (hPSCs), including the requirements for the differentiaton, culture, characterization, quality control (QC), storage, thawing and transport of hPSC-NSCs.

Requirements for the collection of biological source material, the transport to and reception of biological source material and hPSCs at the biobank, as well as the establishment, expansion and QC of hPSCs are covered in ISO 24603.

This document is applicable to all organizations performing biobanking of hPSC-NSCs used for research and development in the life sciences.

This document does not apply to hPSC-NSCs for the purpose of in vivo application in humans, clinical applications or therapeutic use.

NOTE International, national or regional regulations or requirements or multiple of them can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 20387:2018, *Biotechnology — Biobanking — General requirements for biobanking*

ISO 21709:2020, *Biotechnology — Biobanking — Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines*

ISO 24603:2022, *Biotechnology — Biobanking — Requirements for human and mouse pluripotent stem cells*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387, ISO 21709 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
authenticity
quality of being genuine or true

[SOURCE: ISO/TS 22859:2022, 3.1]

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 18162:2024

3.2
biobank
legal entity or part of a legal entity that performs *biobanking* (3.3)

[SOURCE: ISO 20387:2018, 3.5]

3.3
biobanking
process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analyzing and distributing defined biological material as well as related information and data

[SOURCE: ISO 20387:2018, 3.6]

3.4
biorisk
effect of uncertainty expressed by the combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73) of occurrence, where biological material is the source of harm

Note 1 to entry: The harm can be the consequence of an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release.

[SOURCE: ISO 35001:2019, 3.17]

3.5
cell culture
growth of cells dissociated from the parent tissue by spontaneous migration, mechanical or enzymatic dispersal for propagation under in vitro conditions

[SOURCE: ISO/TS 22859:2022, 3.5]

3.6
cell master file
complete dossier of all procedures and records used to generate cells

[SOURCE: ISO/TS 22859:2022, 3.6]

3.7
cell morphology
form and structure of the cell

Note 1 to entry: Morphology can be represented by a single parameter or a combination of two or more parameters.

[SOURCE: ISO 21709:2020, 3.3]

3.8
cell population purity
percentage of a particular cell type in a population, of which has the same specific biological characteristics, such as cell specific markers, genetic polymorphisms and biological activities

[SOURCE: ISO/TS 22859:2022, 3.8]

3.9
cryopreservation
process by which cells are maintained frozen at an ultra-low temperature in an inactive state so that they can be revived at a later time

[SOURCE: ISO 21709:2020/Amd.1, 3.6]

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 18162:2024

3.10
differentiation
process to bring the stem cells into a defined cell state/fate

[SOURCE: ISO/TS 22859:2022, 3.11]

3.11
differentiation potential
ability that refers to the concept that stem and progenitor cells can produce daughter cells which are able to further differentiate into other cell types

[SOURCE: ISO/TS 22859:2022, 3.12]

3.12
flow cytometry
methodologically oriented subdiscipline of analytical cytology that measures cells in suspension in a liquid vehicle as they pass, typically one cell at a time, by a measurement station

Note 1 to entry: The measurement represents transformations of changes in the output of a detector (or detectors) due to changes in scattered light, absorbed light, light emitted (fluorescence) by the cell, or changes in electrical impedance, as the cell passes through the measuring station.

Note 2 to entry: Flow cytometry allows simultaneous evaluation of morphological characteristics of cells (size and internal complexity) with membrane or intracellular antigens.

[SOURCE: ISO/TS 22859:2022, 3.13]

3.13
human neural stem cells derived from pluripotent stem cells
hPSC-NSCs
immature cellular population differentiated from pluripotent stem cells, which has the ability for self-renewal and differentiation to neurons and glia cells (astrocytes or oligodendrocyte) in vitro and in vivo.

Note 1 to entry: Without any manipulation, culture-adapted hNSCs (human neural stem cells) is an alternate term used to denote cells that are different from cells that are found in vivo. It is increasingly clear that these cell types have different properties in terms of gene expression, functionality and phenotype.

3.14
identity verification
part of the process of verifying authenticity of a cell line in which cell origin is genetically confirmed

[SOURCE: ISO 21709:2020, 3.10]

3.15
multipotent cells
cells that have the ability to differentiate into more than one, but a limited number of related cell types

3.16
passage
subculture
process of further culturing of cells in a new culture vessel to provide higher surface area/volume for the cells to grow

[SOURCE: ISO/TS 22859:2022, 3.18]

3.17
passage number
number of subculturings that occurred

Note 1 to entry: For this document P_0 is understood as the starting population of the cells.

[SOURCE: ISO 21709:2020, 3.13, modified — Note 1 to entry has been added.]

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 18162:2024